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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,194	01/29/2004	Bret A. Ferree	BAF-16802/29	5735

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GIFFORD, KRASS, SPRINKLE, ANDERSON & CITKOWSKI, P.C  
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EXAMINER
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STEWART, ALVIN J

ART UNIT	PAPER NUMBER
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3774

MAIL DATE	DELIVERY MODE
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12/10/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/767,194

Applicant(s)

FERREE, BRET A.

Examiner

Alvin J. Stewart

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,7,8,13-15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,7,8,13-15 and 18-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

***Election/Restrictions***

The Examiner has withdrawn claim 17 because it belong to a non-elected species. See respond to restriction filed on 07/13/06.

***Response to Arguments***

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

The Examiner made a new rejection regarding the Zacouto reference in order to clarify the Examiner's rejection and added new rejections.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 7 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In claim 7, line 2, the applicant positively recites part of a human, i.e. "into a vertebral body". Thus, claim 7 include a human part within the scope of the invention and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F. 2d 897, 164 USPQ 636 (CCPA 1970).

In order to overcome this rejection the Applicant's representative has to rephrase the as follow: "are capable or adapted to press fit into a patients vertebral body."

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5, 7, 8, and 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "surface" in line 3. There is insufficient antecedent basis for this limitation in the claim. It should say "the surface".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5, 13-15, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Zacouto US Patent 6,692,495 B1.

Zacouto discloses an artificial disc comprising an endplate (10) (the Examiner is interpreting the two separate fixators 10 in Fig. 14 as the endplate) having a surface (25b) with a cooperating component (see below 25 disclosed in the same embodiment shown in col. 8, lines 21-24) wherein the surface of the endplate is formed with separate components (see attachment disclosing the two separate fixators 10) that are physically configured for

assembly within an intervertebral disc space (see Fig. 15; see col. 8, lines 27-50, the examiner two separate devices connect to each other when they are inserted within the intervertebral disc).

Regarding claim 2, see col. 8, lines 50-61 disclosing a bellow having a viscoelastic material.

Regarding claim 5, see the other metal alloy (see col. 4, lines 38-40).

Regarding claims 13-14, see col. 8, lines 21-61.

Regarding claim 14, the bellows are manipulated to achieve a vertebral distraction function.

Regarding claim 15, see screw rods (40) interpreting the retaining elements.

Regarding claims 18, see col. 8, lines 27-40 disclosing a first component (first fixator) connected from a right posterior route and a second component (second fixator) connected from a left posterior route and then abutting each other.

Claims 1, 7, 8, 18 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Taylor US Pat. Pub. 2004/0254644 A1.

Taylor discloses an artificial disc comprising an endplate (511, see Figs. 17-19) having a surface that articulate with a cooperating component (see Fig. 19, see dome in element 570) wherein the surface of the endplate is formed with separate components (518) that are physically configured for assembly within an intervertebral disc space.

Line 4, has been identified as an intended use limitation because is typical of claim limitations which may not distinguish over prior art according to the principle. It has been held

that the recitation that an element is “configured to” performing a function is not a positive limitation but only requires the ability to so perform..

Regarding claim 7, in Figure 17 elements 520 and 524 make the two separate components (518) press fit to the patient’s vertebral body.

Regarding claim 8, see different embodiment disclosing a snap-fit engagement (see Figs. 11 and 12 and paragraph 79.

Regarding claims 18 and 20, the Examiner interpreted the endplate as element 18, see Figs. 1-4 ) having a surface (20 and 68) that articulate with a cooperating component (80) wherein the surface of the endplate is formed with separate components (elements 18 and 34) that are physically configured for assembly within an intervertebral disc space.

Regarding the word “situ” in claim 18, the examiner interpreted the element 34 as being assembled in situ because the wedge (34) has to be moved within the implant after the implant is completely inserted within the patient’s disc cavity.

Regarding claim 20, the examiner interpreted the second element 34 in the lower section of Figure 2 as the spacer that also is assembled in situ.

Claims 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Boyd et al US Patent 6,468,311 B2.

Boyd et al discloses a method of implanting an artificial disc comprising the steps of providing an endplate (10) constructed from a first (12) and second components (13), installing the first component into an intervertebral disc space and installing the second component into the disc space by attaching the second component to the first component, thereby assembling the endplate in situ (see Figs. 8-12).

Regarding claim 19, see col. 6, line 66- col. 7, line 6.

Regarding claim 20, see Fig. 2 element 28.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*A. Stewart*  
**ALVIN J. STEWART**  
**PRIMARY EXAMINER**  
AU 3774

November 29, 2007.

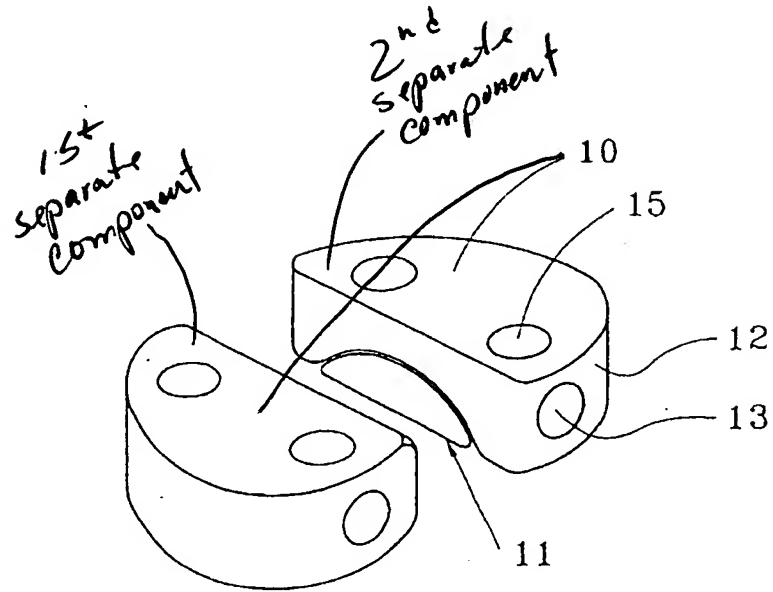


FIG. 14

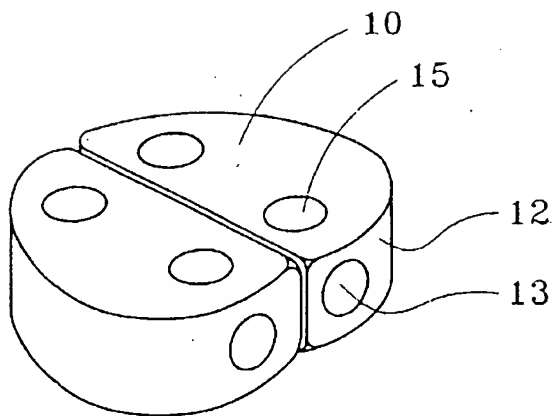


FIG. 15

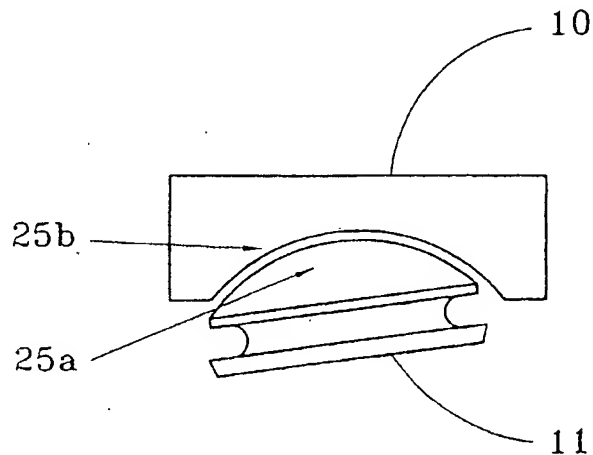


FIG. 16